



DEPARTMENT OF HEALTH & HUMAN SERVICES

Kovell

Food and Drug Administration
Rockville MD 20857

OCT 2 2001

Re: da VINCI System
Docket No. 01E-0095

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

#21

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,808,665 filed by SRI International under 35 U.S.C. § 156. The medical device claimed by the patent is the da VINCI System, which was assigned premarket approval application (PMA) No. P990079.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The 510(k) application was approved on July 11, 2000, which makes the submission of the patent term extension application on September 11, 2000, not timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Kenneth R. Allen, Esq.
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